UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

UNITED STATES OF AMERICA, ex rel. PAUL CAIRNS, et al.,	)	
Relators,	)	
v.	)	No. 1:12 CV 00004 AGF
D.S. MEDICAL, L.L.C., et al.,	)	
Defendants.	)	

UNITED STATES' OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS BASED ON RULE 12 (b)(6) AND RULE 9(b)

Plaintiff, the United States of America, respectfully files this consolidated response to Defendants' motions to dismiss pursuant to Rule 12(b) (Docket #64) and Rule 9(b) (Docket # 65) and requests that the Court deny both of Defendants' motions to dismiss. The Government's Complaint-in-Intervention (Complaint, Docket #26) states plausible claims upon which relief can be granted, and provides the Defendants with sufficient particularity to enable them to respond to the allegations.

I. FACTUAL BACKGROUND

This civil action is brought under the False Claims Act (FCA), 31 U.S.C. § 3729-33. The initial complaint was filed by a group of seven relators on January 5, 2012. The United States conducted a diligent investigation, and subsequently intervened in the case. On July 9, 2014, the Government filed its Complaint.

The Complaint alleges that Defendants Dr. Sonjay Fonn and his fiancée, Deborah Seeger, conspired to violate the Medicare Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b and the FCA by incorporating a distributorship for spinal surgical supplies called D.S. Medical, L.L.C.

(DSM) in Ms. Seeger's name. (Complaint ¶ 6). Although Dr. Fonn was not a shareholder, officer, or employee of DSM, he played an important management role for the company. (Complaint ¶¶ 50-54). Further, in exchange for using their products, Dr. Fonn expected manufacturers of spinal implant devices to retain DSM as a distributor of their products and to pay it a substantial commission, despite the fact that Ms. Seeger had no prior experience or expertise in the operation or management of a medical device distributorship. (Complaint ¶¶ 23-29, 46-49).

Dr. Fonn, who enjoyed surgical privileges at a local hospital in the Cape Girardeau area, would inform the hospital that he wanted to use the products made by certain manufacturers during his surgeries, with the implant manufacturers using DSM as their distributor. (Complaint ¶¶ 30-32, 38-42). The hospital would arrange to purchase the requested devices. (Complaint ¶¶ 33, 38-42). If the patient was a Medicare or Medicaid beneficiary, the hospital sought and received reimbursement for the cost of the implants by filing claims with the Medicare or Medicaid programs. (Complaint ¶¶ 34, 42). In addition, Dr. Fonn, acting through Midwest Neurosurgeons, L.L.C. (MWN) directly submitted claims to and was paid by the Medicare and Medicaid programs for his professional services associated with the aforementioned surgeries. (Complaint ¶ 35).

The manufacturers, including spinal implant manufacturers A and B[1], paid DSM a percentage of the price paid by the hospital on the purchases as a commission. (Complaint ¶¶ 33, 54-60). Once DSM was established, virtually all of the surgical implant devices used by Dr. Fonn were purchased with DSM as the distributor. Dr. Fonn was DSM's only

[1] Neither the spinal manufacturers nor the hospital are named as parties in the Complaint. Accordingly, their identities have not been disclosed in the Complaint. However, the United States advised the Defendants of the identities of these two entities at a meeting on May 12, 2014.

physician/customer, and the only doctor using DSM at his hospital. (Complaint ¶¶ 38-42). Once DSM opened, Dr. Fonn altered his surgical practices, increasing the number of implants he used during surgeries. (Complaint ¶¶ 61-66).

The commissions paid to DSM were deposited into DSM bank accounts. (Complaint ¶¶ 69-70). These accounts were used by Ms. Seeger to purchase a residence where she and Dr. Fonn resided, and were also used to pay for various improvements to the residence. Ms. Seeger also used the funds to purchase commercial real estate which was later sold to Dr. Fonn. Ms. Seeger also used the commissions to purchase other items such as cars and boats which she shared with Dr. Fonn. (Complaint ¶¶ 45, 70-71).

In summary, Dr. Fonn used his medical decision making power to steer business to his fiancée, Ms. Seeger, and her company, DSM. Together, they operated DSM and shared the proceeds of this illegal referral pattern. Their conduct caused the hospital where Dr. Fonn performed his surgeries and Dr. Fonn's company, MWN, to both file claims with the Medicare and Medicaid programs which were tainted by the Defendants' kickbacks and were, therefore, false.

Based on the foregoing facts, the Complaint alleges three related but distinct causes of action under the FCA.

- Count I alleges that Dr. Fonn solicited and received remuneration from Ms. Seeger and DSM, and Ms. Seeger and DSM offered and paid remuneration to Dr. Fonn in the form of the use of a home and improvements to the home, as well as other items such as cars and boats. This remuneration was intended to induce Dr. Fonn into arranging for or recommending the hospital's purchase of spinal implants for which payment was made in whole or in part by the Medicare and/or Medicaid programs through DSM.

- Count II alleges that Dr. Fonn, Ms. Seeger, and DSM solicited and received remuneration from spinal implant manufacturers A and B in the form of commissions and other payments to DSM. This remuneration was intended to induce Dr. Fonn, Ms. Seeger, and DSM into arranging for or recommending the

hospital's purchase of spinal implants for which payment was made in whole or in part by the Medicare and/or Medicaid programs from spinal implant manufacturers A and B versus other competitors in the implant industry.

- Count III alleges that Dr. Fonn and Ms. Seeger conspired individually, and through DSM and MWN, to solicit and receive remuneration from multiple spinal implant manufacturers in the form of commissions and other payments to DSM. This remuneration was intended to induce the Defendants into arranging for or recommending the hospital's purchase of spinal implants for which payment was made in whole or in part by the Medicare and/or Medicaid programs from the spinal implant companies using DSM and paying the commissions.

The Complaint also alleges common law causes of action for Payment Under Mistake of Fact (Count IV) and Unjust Enrichment (Count V) based on the foregoing allegations.

II. RELEVANT LAW

A. The Anti-Kickback Statute

The AKS prohibits any person from "knowingly and willfully" soliciting, receiving, offering, or paying "remuneration" in the form of a kickback, bribe, rebate, or anything of value to induce another to "purchase, lease, order, *or arrange for or recommend* purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §§ 1320a-7b(b)(1)(B) and 7b(b)(2)(B) (emphasis added). Remuneration is broadly construed, and is intended to include "anything of value." *Klaczak v. Consolidated Med. Transp.*, 458 F.Supp.2d 622, 678 (N.D.Ill. 2006); *see also* 56 Fed.Reg. at 35958 ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever."); *United States v. Bay State Ambulance*, 874 F.2d 20, 29–31 (1st Cir. 1989) (finding that "Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."). The AKS is violated whenever one purpose of a payment is to induce future referrals or to compensate for past referrals. *U.S. v.*

Borrasi, 639 F.3d 774, 782 (7th Cir. 2011) ("We join our sister circuits in holding that if part of the payment compensated past referrals or induced future referrals, that portion of the payment violates [the AKS.]"); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) ("If one purpose of the payment was to induce future referrals, the Medicare statute has been violated."); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989) ("[T]he Medicare fraud statute is violated if 'one purpose of the payment was to induce future referrals.'"); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("This court agrees with the sound reasoning in *Greber* and thus holds that a person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.").

B. The False Claims Act

The False Claims Act is "the Government's primary litigative tool for combating fraud." S. Rep. No. 99-345, 99th Cong., 2d Sess. 2, reprinted in 1986 U.S.C.C.A.N. 5266. When enacting the False Claims Act, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.' " *Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

The FCA imposes civil liability when a person "knowingly presents, or causes to be presented" to the Government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Id. § 3729(a)(2).[2]

[2] These citations are to the FCA as it existed before it was amended in 2009. The corresponding citations in the Fraud Enforcement and Recovery Act of 2009 ("FERA") are 31 U.S.C. § 3729(a)(1)(A) and (B), respectively. Public Law 111-21. Both the pre- and post-FERA versions of the FCA apply to this case depending on the time period, but the result is the same under

As part of the comprehensive health care reform legislation enacted in 2010, Congress amended the AKS to clarify that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)). Although the amendment is not retroactive, it confirms that claims tainted by kickbacks are "false" within the meaning of the False Claims Act, and it is thus persuasive evidence of how claims made prior to the effective date of the new legislation should be treated. *Loving v. United States*, 517 U.S. 748, 770 (1996) ("[s]ubsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction."); *Bates v. United States*, 522 U.S. 23, 32 (1997) (rejecting argument that clarifying amendments demonstrated that prior version of statute did not cover the conduct in question).

Even before the 2010 amendments, the overwhelming majority of courts which considered the question held that violation of the AKS makes a subsequent claim for payment by Medicare or Medicaid actionable under the FCA. *See generally United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011); *United States ex rel. Kosenske v. Carlisle HMA, Inc.* 554 F.3d 88 (3rd Cir. 2009);*United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997); *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008); *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005); *United States ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp. 2d 28 (D.D.C. 2003); *United States ex rel. Pogue v. Diabetes Treatment Centers*, 238 F. Supp. 2d 258 (D.D.C. 2002); *United*

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either version. To avoid unnecessary complexity, all citations in this brief are to the pre-FERA version of the FCA.

States ex rel. Health Dimensions Rehabilitation, Inc. v. RehabCare Group, Inc., 2013 WL 992642 (E.D. Mo. March 13, 2013) (*RehabCare I*).

Taken together, these decisions and the 2010 amendments recognize that the structure of the Anti-Kickback Statute, and the role it plays in ensuring the reliability and integrity of referrals and resulting claims, render it a core term of the Federal health care programs – a provision with which Congress and the programs require compliance as a condition of payment. *Greber*, 760 F.2d at 71-72.

C. Federal Rule of Civil Procedure 12(b)(6) Standards

Fed. R. Civ. Proc. 8(a)(2) requires a "short and plain statement of the claim showing that the pleader is entitled to relief. When deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), and measuring whether Rule 8(a)(2) is satisfied, the Court determines whether the complaint contains "sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Hamilton v. Palm*, 621 F.3d 816, 817 (8th Cir. 2010) (for Rule 12 purposes, even a "facially conclusory" allegation is sufficient, without the need for a "recitation of all potentially relevant facts"). Determining whether a claim is "plausible" is a "context specific task that requires the Court to draw on its judicial experience and common sense." *Twombly*, 550 U.S. at 1950; *Hamilton*, 621 F.3d at 818.

Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In sum, the standard under Rule 12(b)(6) "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

D. Federal Rule of Civil Procedure 9(b) Standards

Fed. R. Civ. P. 9(b) applies to actions brought under the FCA. *United States ex. rel Joshi v. St. Lukes Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). The overarching purpose of Rule 9(b) is "to enable defendants to respond specifically, at an early stage of the case, to potentially damaging allegations of immoral and criminal conduct." *BJC Health Sys. v. Columbia Cas. Co.*, 478 F.3d 908, 917 (8th Cir. 2007). As a result, "conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Id.* However, Rule 9(b)'s particularity requirement does not mute the general principles set out in Rule 8 that a complaint need only provide a "short and plain statement of the claim; rather, the two rules must be read in harmony." *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001), *quoting Michaels Bldg. Co. v. Ameritrust Co.*, 848 F.2d 674, 679 (6th Cir. 1988).

To meet Rule 9's standards, the complaint "must identify the who, what, where, when, and how of the alleged fraud." *Joshi*, 441 F.3d at 556. While Rule 9(b) does not require a plaintiff "to allege specific details of every alleged false claim," the plaintiff must provide "some representative examples" of fraudulent conduct. *Id.* at 557; *see also RehabCare I,* 2013 WL 992642). In a Rule 9(b) motion, the court accepts as true the factual allegations contained in the complaint and draws all reasonable inferences in favor of the nonmoving party." *Drobnak v. Andersen Corp.*, 561 F.3d 778, 781 (8th Cir. 2009); *United States ex rel. Sandager v. Dell Mktg., L.P.*, 872 F.Supp.2d 801, 812 (D.Minn. 2012).

III. ARGUMENT

Typically, defendants in FCA cases file a single motion raising both Rule 12 and Rule 9 challenges. In this case, Defendants have chosen to file two separate motions. Nonetheless, given the considerable overlap in the arguments raised in the two motions, the government will

file a single Response, addressing first Defendants' Rule 12(b)(6) motion, and then the Rule 9(b) motion.

A. THE COMPLAINT-IN-INTERVENTION SATISFIES THE REQUIREMENTS OF RULE 12(b)

The Defendants' Motion to Dismiss Pursuant to Rule 12(b) sets forth several arguments. This brief responds to each argument, using the order of Defendant's brief.

1. Defendants' "But-For" Causation Arguments Have Been Rejected By Multiple Courts

Defendants' primary argument for dismissal, found at pages 2-13 of their brief in support of their Motion to Dismiss Pursuant to Rule 12(b) (Docket #68), is based on a fundamental misunderstanding of the 2010 amendment to the AKS. That amendment, codified at 42 U.S.C. § 1320a-7b(g), provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." Defendants argue that the AKS amendment's use of the phrase "resulting from" now injects a new – and more stringent – "but for" cause requirement into the standard of falsity under the FCA, and requires the Government to formally plead that all items or services provided under an illegal kickback relationship were medically unnecessary and would not have been referred without the bribes or kickbacks inducing the doctor's referral.

Defendants' "but for" causation arguments borrow heavily from a brief recently filed by a large drug company in a FCA case now pending in the Southern District of New York. The district court in that case rejected the "but for" argument after reviewing the legislative history behind the 2010 AKS amendment, finding it merely clarified well-established law (cited in Section II.B., above) that any claims submitted under an illegal kickback relationship are false

for FCA purposes. *United States ex rel. Kester v. Novartis Pharm. Corp.*, __ F.Supp.3d __, 2014 WL 4230386, pp. 6-11 (S.D.N.Y. August 7, 2014).

Numerous other courts have reached the same conclusion as the *Kester* court that the 2010 AKS amendment clarified and did not change the principle that any claim presented to a federal health care program from a referral relationship that violates the AKS is a "false claim" for purposes of the FCA. *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 312 n. 19 (3rd Cir. 2011) (2010 amendment was a clarification); *United States ex rel. Brown v. Celgene Corp*., 2014 WL 3605896 (C.D. Cal. 2014) (denying motion to dismiss FCA complaint and noting 2010 AKS amendment merely clarified well-established law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act); *United States ex rel. Williams v. Health Management Assoc., Inc.*, 2014 WL 2866250 (M.D. Ga. June 24, 2014) (finding compliance with AKS was a condition of payment, before or after the 2010 AKS amendment); *United States ex rel. Booker v. Pfizer, Inc.*, 2014 WL 1271766 (D. Mass. March 26, 2014) (denying motion to dismiss AKS/FCA case where relator failed to allege services provided under kickback relationship were not fair market value after noting 2010 amendment); *Hendricks v. Lincare Inc.*, 2014 WL 1225660 (E.D. Pa. Mar. 25, 2014), *United States ex rel. Parikh v. Citizens Medical Ctr*., 977 F.Supp.2d 654, 664 n.3 (S.D. Tex. 2013); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52-53 (D. Mass. 2011) (the 2010 AKS amendment "was intended . . . to clarify the reach of the Anti–Kickback Statute, which had been called into question by recent litigation").

These cases correctly interpret the scope and meaning of the 2010 AKS amendment. Courts "assume that, when Congress enacts statutes, it is aware of relevant judicial precedent." *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 648 (2010). Thus, how courts had analyzed falsity

in FCA cases involving kickbacks was a key context for the AKS amendment. Prior to 2010, numerous courts had already rejected the argument that the Defendants make here – that the AKS required some showing that kickbacks had caused the use of an item or provision of a service that was not medically necessary. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp*., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998); *United States ex rel. Pogue v. Am. Healthcorp, Inc*., 914 F. Supp. 1507 (M.D. Tenn. 1996). These cases recognized that the government – and Congress – had no confidence in the integrity of any claim for an item or service tainted by kickbacks, without the need for a case-by-case medical record review.

As courts have recognized, an AKS violation makes any claims submitted under the illegal relationship "false," with no need to subtract the "fair market value" of the services when calculating damages. *United States ex rel. Health Dimensions Rehabilitation, Inc. v. RehabCare Group, Inc.*, 2013 WL 5340910 (E.D. Mo. Sept. 23, 2013) (*RehabCare III*) (finding the measure of damages was the full amount of the claim, with no reduction for the alleged value of the services or need to show the claims exceeded fair market value). As explained in *Rogan*, the Government conditions payment on compliance with the AKS. 517 F.3d at 453. Thus, it does not matter for purposes of the FCA whether if "the patients had gone elsewhere, the United States would have paid for their care" or "perhaps the patients, or a private insurer, would have paid for care at [the defendant] had it refrained from billing the United States." *Id*. In other words, a claim triggers liability under the FCA if it is linked to or tainted by a kickback violation – including "soliciting" and "recommending" items or services – and the Government is not required to show either that the items or services were, in fact, medically unnecessary or that the kickbacks actually "succeeded" in inducing referrals. In fact, Congress purposely wrote the

AKS to avoid the need for such a case-by-case showing. *See* H.R. Rep. 95-92 (1977), 95th Cong., 1st Sess. at 47, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3050 (in enacting the AKS, Congress recognized that, because "the medical needs of a particular patient can be highly judgmental," "it is difficult" to identify or prove "excessive services").

The legislative history of the 2010 amendment shows that Congress intended "to strengthen," rather than to curtail, "fraud enforcement." *See* 155 Cong. Rec. S10852, 10854, 2009 WL 3460582, at *S10854. Other parts of the same bill that ultimately became the 2010 amendment provided harsher criminal sentences for health care fraud offenses while relaxing the *scienter* requirements for some offenses. *Kester*, 2014 WL 4230386 at 8. Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose." *Abramski v. United States*, 134 S. Ct. 2259, 2267 (June 16, 2014). Given this legislative context, the 2010 AKS amendment cannot fairly be read to create a higher FCA/AKS proof burden at the same time as it made the prosecution and punishment of health care offenses easier.

The Supreme Court has deemed the FCA a remedial statute. *United States v. Neifert-White Co.*, 390 U.S.228, 233 (1968). Where the term "resulting from" or a similar term is used in a statute that has a remedial purpose, courts have refused to find rigid "but for" causation requirements. *Paroline v. United States*, 134 S. Ct. 1710, 1727 (2014) (declaring it "unacceptable to adopt a causal standard so strict that it would undermine Congressional intent where neither the plain text of the statute nor legal tradition demands such an approach"); *Nat'l Ass'n of Mfrs. v. United States Dep't of Interior*, 134 F.3d 1095, 1103 (D.C. Cir. 1998) (term "resulting from" in CERCLA did not impose "a burden to demonstrate that a particular release in fact caused injury to a specific natural resource").

Instead of narrowing the reach of the AKS and the FCA, the legislative history shows that Congress wanted to counteract a minority judicial view that Congress deemed contrary to the purpose of the AKS, especially the district court decision in *United States ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008). *See* 155 Cong. Rec. S10852, 10854, 2009 WL 3460582, at *S10853. (Senator Kaufman stating that the amendment was intended to "remed[y] the problem" created by a court decision insulating kickback recipient from liability under the FCA); *Kester*, 2014 WL 4230386 at pp. 8-9. Defendants' brief at pp. 27-28 relies heavily on the *Thomas* case, ignoring the fact that Congress soundly rejected that case's reasoning and it was against the weight of the caselaw even before the 2010 amendment.

Finally, Defendants' arguments ignore the plain text of the statute, as nothing in the amendment discusses the need to prove that claims submitted under an illegal kickback relationship were also "medically unnecessary." This Court should not read the 2010 amendment to impose absurd consequences. Under Defendants' counter-intuitive reading of the amendment, Defendants could be convicted of criminal conduct under the AKS with or without proof of medically unnecessary services, but would be insulated from civil FCA liability for the exact same conduct, absent additional proof that each surgery and each implant was medically unnecessary. The Court should reject such an absurd reading of Congress' 2010 amendment of the AKS.

2. The Government's Complaint in Intervention Makes Plausible And Sufficient Allegations of Illegal Remuneration and Violations of the Anti-Kickback Statute

This opposition next turns to the arguments found at pp. 13-25 of Defendants' brief in support of their Rule 12(b) motion, where Defendants erroneously argue that the benefits Dr. Fonn enjoyed as a result of the scheme did not constitute "remuneration" or an inducement of

referrals under the AKS. The Government's Complaint, however, does state claims upon which relief can be granted. It explicitly tracks the statutory language of the AKS and formally alleges that both Defendants Dr. Fonn and Ms. Seeger, as well as their corporate entities, violated the AKS, and both individuals received illegal remuneration. *See* Complaint, Docket #26, ¶¶ 81, 87, 70-71. In sum, the Complaint alleges facts from which a reasonable factfinder could conclude that Dr. Fonn and his fiancée, Ms. Seeger, conspired to leverage Dr. Fonn's medical decision making power, leading spinal implant manufacturers to retain and pay commissions to DSM, a company owned by Ms. Seeger, and that Ms. Seeger shared the proceeds of this illegal referral pattern with Dr. Fonn. Dr. Fonn's insistence that the hospital order implants for his surgeries from spinal device manufacturers willing to "play ball" by maintaining DSM as a distributor, the commission payments made by the manufacturers to DSM, Ms. Seeger's sharing the beneficial use of those commissions with Dr. Fonn, and the conspiracy between Dr. Fonn and Ms. Seeger, taken together clearly state AKS violations. As alleged in the Complaint, the AKS prohibited the giving or receiving of remuneration (i.e., the commission payments to DSM) where one purpose of that remuneration was to induce Dr. Fonn to "arrang[e] for or recommend[ing]" the particular spinal implant devices to be used by Dr. Fonn during surgeries funded by Medicare and Medicaid.

Defendants acknowledge the intimate relationship between Dr. Fonn and Ms. Seeger, but implausibly argue that their kickback scheme with the spinal implant manufacturers was just "normal conduct" between "life partners." This argument asks the Court to flip the Rule 12(b)(6) standard of review on its head and accept as true the conclusory and self-serving assertions made in the Defendants' motion – rather than the well-pled facts in the Government's Complaint. The Complaint's Exhibit 1 shows that the stereo equipment, landscaping, and kitchen improvements

and other items, many personally selected by Dr. Fonn, that were funded by Seeger's commission revenue, by themselves totaled in the seven figures. These facts plausibly show that the commissions paid by the manufacturers to induce Dr. Fonn to use their implants constituted a "benefit" to Dr. Fonn, as well as to his fiancée, and went far beyond basic household necessities.

Critically, the Complaint highlights Defendants' *business* activities -- Dr. Fonn's choice to use his fiancée's company as his sole source distributor, Dr. Fonn's operational role negotiating prices for DS Medical's implants, Seeger's negotiating tactics of claiming control over the spinal implant treatment choice with implant manufacturers, and both Dr. Fonn and Seeger's receipt of millions of dollars' worth of remuneration from implant manufacturers through Seeger's 50% commissions for the implants used in each of Dr. Fonn's surgical implants. As such, Defendants' money-making business activities, as alleged in the Complaint, did not occur (as Defendants claim) "in a private realm of family life," but instead directly involved actual patients receiving implants from DSM during Dr. Fonn's surgeries, followed by substantial payments from the Medicare and Medicaid programs.

The Complaint's allegations must be measured against the AKS' broad definition of remuneration. The statute prohibits not just cash payments to a referral source, but the transfer of any "remuneration," in cash or in kind, flowing to the doctor for arranging the purchase of any federally funded medical item or service. "Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever." 56 Fed. Reg. 39592, 35958 (July 29, 1991). The AKS forbids "any remuneration knowingly and willfully offered, paid, solicited, or received in exchange for Medicare or Medicaid patient referrals." *United States v. LaHue*, 261 F.3d 993, 996 (10th Cir. 2001). The meaning of "remuneration" is therefore interpreted broadly: it means "anything of

value in any form whatsoever." *United States ex. rel. Fry v. The Health Alliance of Greater Cincinnati,* No. 1:03–CV–001672008, 2008 WL 5282139, at *7 (S.D. Ohio Dec. 18, 2008).

Further, these allegations must further be measured against the "one purpose" legal standard of the AKS. A person could hypothetically give another person remuneration for a variety of reasons, including love and affection, but if one purpose of the remuneration is to induce referrals, then the remuneration is illegal. *United States ex rel. Health Dimensions Rehabilitation, Inc. v. RehabCare Group, Inc.*, 2013 WL 4666338, 2013 (E.D. Mo. Aug. 30, 2013) (*RehabCare II*); *see also Greber*, 760 F.2d at 69 (even if the physician had received some money for legitimate services and some money for illicit referrals, the purpose of the statute was frustrated); *Borrasi*, 639 F.3d at 782; *McClatchey*, 217 F.3d at 835; *Kats*, 871 F.2d at 108; *Davis*, 132 F.3d at 1094.

The AKS has numerous exceptions and safe harbors, enabling discounts and other business arrangements, but there is no exception for large repeated payments between "life partners" who happen to be a neurosurgeon and a fiancée/implant distributor.

Granted, Seeger can testify at trial that her intent in spending millions on Dr. Fonn was just to show affection. Dr. Fonn can testify he only managed DS Medical to help his fiancée succeed. In response, the Government can present evidence that both Defendants did these activities to benefit themselves financially, and to leverage Dr Fonn's implant referral power. For now, the Court should not try to resolve these evidentiary issues with a Rule 12 motion.

The Government agrees with Defendants' motion at p. 23 that if Fonn and Seeger were married, then their conduct would also be illegal under another federal statute, the Stark Act, 42 U.S.C. § 1395nn, as that law generally prohibits a hospital from having a financial relationship with the immediate family member of a referring physician. But the AKS is not limited to

arrangements between hospitals and physicians' spouses and children. Thus, the Defendants' unmarried status does not immunize them from liability under the AKS and the FCA, where the Complaint properly alleges that Dr. Fonn shared the benefits of the kickback scheme he arranged and nurtured for his live-in partner. The fact that Defendants elected to remain unmarried, apparently to avoid the Stark Law's prohibitions, demonstrates Defendants' knowledge that their conduct was wrongful and thus further supports the Government's allegations.

In conclusion, taking the Complaint as a whole, and properly applying the broad definition of "remuneration" and the one purpose test, the Complaint easily survives scrutiny under Rule 12, and states plausible FCA/AKS claims upon which relief can be granted. A complaint need not rule out or rebut all possible lawful explanations for a Defendant's conduct. Rather, the complaint is construed "most favorably" to the non-moving party. *Braden v. Wal-Mart Stores*, 588 F.3d 585, 596-97 (8th Cir. 2009) (holding complaint must be read as a whole, not parsed be piece by piece). Where the Defendants have enough detail to inform them of the core factual basis of the claims, and the complaint states a plausible basis for relief, the Rule 12 motion should be denied. *RehabCare I*, 2013 WL 992642 at *3.

3. The Government's Complaint in Intervention Makes Plausible And Sufficient Allegations of Certification

At pp. 25-29 of their Rule 12(b) motion, Defendants argue that they are insulated from liability because a hospital where the spinal surgeries were performed submitted some of the claims for Dr. Fonn's surgeries, and only the hospital certified compliance with the AKS in its enrollment agreement with the Medicare program. Defendants' sole "support" for this argument is a District of Arkansas case, *United States ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008). As discussed earlier in this brief, Congress believed that *Thomas* was wrongly decided, and enacted the 2010 AKS amendment to ensure that Courts would take a

different approach. *Kester*, 2014 WL 4230386 at 8. Having been an outlier ruling to begin with, and having been expressly rejected by Congress, *Thomas* provides no viable support for Defendants' position.

Moreover, Defendants overlook several key allegations. First, the Complaint alleges that Dr. Fonn personally made a number of certifications in his Medicare enrollment application, including an explicit acknowledgement by him that compliance with the AKS was a precondition of payment by Medicare (¶¶ 16-17).

Second, the Complaint alleges that Dr. Fonn personally submitted a number of Part B physician services claims for his examination of surgical implant patients shortly after their surgeries with DS Medical's implants. (¶ 19).

Finally, the Complaint at ¶¶ 83, 88 alleges that both Defendants *caused* the submission of the false claims by the hospital, even if the hospital was the entity actually presenting the Part A surgical claims to federal programs. Together, these allegations are sufficient to state a claim upon which relief can be granted. *Blackstone*, 647 F.3d at 389-90 (reviewing cases holding that non-submitting entity may be liable under the FCA for causing another to submit false claims, and holding that a hospital's certification to comply with the AKS does not insulate a spinal implant company from FCA liability for paying bribes to doctors to use its Medicare-funded implants).

Section 3729(a)(1) of the FCA generally prohibits any person from making, or causing to be made, false or fraudulent claims for payment from the Government. 31 U.S.C. § 3729(a)(1). The provision does not require, or even mention, the need for a "false certification." The majority of circuit courts have by now recognized that Section (a)(1) does not require an "express" certification of compliance with a condition of payment in order for a valid FCA

action to exist. Rather, courts have overwhelmingly recognized that Section 3729(a)(1) encompasses claims that, through their submission, imply compliance with statutory, regulatory, or contractual prerequisites to, or conditions of, payment. *See, e.g., United States ex rel. Hobbs v. Medquest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013) (recognizing that a false certification theory applies "where the underlying regulation is a 'condition of payment,' meaning that the government would not have paid the claim had it known the provider was not in compliance"*); U.S. ex rel. Wilkins v. United Health Group*, 659 F.3d 295, 306-07 (3d Cir. 2011) ("to plead a claim upon which relief could be granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government. . . . '[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.'" *(quoting United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 *(10th Cir. 2008); Blackstone*, 647 F.3d at 394-95 ("Express contractual language may constitute dispositive evidence of materiality, but materiality may be established in other ways, such as through testimony demonstrating that both parties to the contract understood that payment was conditional on compliance with the requirement at issue" (internal citation and quotations omitted)*; United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1271 (D.C. Cir. 2010)* ("To establish FCA liability under an implied certification theory, the plaintiff must prove by a preponderance of the evidence that compliance with the legal requirement in question is material to the government's decision to pay")*; United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) ("The violation of the [Medicare] regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claims false under section 3729(a)(1)")*; but see*

United States ex rel. Mikes v. Straus, *274 F.3d 687, 700 (2d Cir. 2001*)("implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid"). The Eighth Circuit concurs in the majority view. *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011) (citing *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1219 (10th Cir. 2008). That is exactly what the Complaint alleges here at ¶¶ 16-17. In sum, it is well-settled – and now confirmed by Congress – that compliance with the AKS is a condition of payment by Medicare or Medicaid. The complaint's allegations regarding certification are sufficient.

4. Medicaid Is a Federal Program

At pp. 30-31 of their motion, Defendants argue that the Complaint improperly alleges AKS and FCA violations based upon claims submitted to, and paid by, the Medicaid program because the State of Missouri, and not the federal government, administers that program and processes the claims. Defendants ignore the fact that Medicaid claims are paid, in part, with federal funds. Defendants' clumsy argument is resolved by the FCA's definition of a "claim." Under 31 U.S.C. § 3729(c), the FCA covers not just claims made directly to a federal agency but also "any request or demand ... for money... which is made to a contractor, grantee, or other recipient if the United States provides any portion of the money...." Applying this broad definition, courts have uniformly recognized that Medicaid is a federal program for FCA purposes. *United States v. Cathedral Rock*, 2007 WL 4270784 (E.D. Mo. November 30, 2007) (denying Rule 12 motion as fraud upon Medicaid "falls squarely within the ambit of the FCA"); *United States v. Adler*, 623 F.2d 1287 (8th Cir. 1980) (affirming conviction for submitting false

claims to the Missouri Medicaid program under 18 U.S.C. § 287); *United States ex rel. Tyson v. Amerigroup*, 2005 WL 2667207 (N.D. Il. 2005) at p. 3.

Further, the AKS itself specifically encompasses the submission of kickback-tainted claims to the Medicaid program, as well as to the Medicare program. In 42 U.S.C. § 1320a-7b(f), the term "federal healthcare program" is defined to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," as well as "any State health care program" including Medicaid. Courts have acknowledged that the AKS applies to the Medicaid program. *See, e.g.*, *New York v. Amgen*, 652 F.3d 103, 112-13 (1st Cir. 2011) (reversing district court's dismissal of complaint alleging Medicaid AKS/FCA violations because the absence of bribes and kickbacks is a precondition of payment for Medicaid claims).

Moreover, the Missouri Medicaid program has its own Anti-Kickback provisions that closely track federal law. Mo. Rev. Stat. § 191.905(1) (prohibiting providers from causing the submission of false Medicaid claims); § 191.905(2) (prohibiting the knowing solicitation or receipt of remuneration, including any kickback, or bribe, directly or indirectly, overtly or covertly, in cash or in kind, in return for ordering, arranging for, or recommending the purchasing any health care). Thus, compliance with both the federal and Missouri state versions of the AKS are conditions of payment, and the complaint's Medicaid allegations are, accordingly, sufficient.

5. The Complaint Adequately Alleges Unjust Enrichment and Payment by Mistake Claims in Counts IV-V

At pages 31-35, Defendants' motion raises a number of technical and evidentiary arguments against Count IV and V's common law claims. Given the broad and flexible nature of these remedial claims, Defendants' arguments fail.

The Supreme Court has long recognized the "Government's long-established right to sue for money wrongfully or erroneously paid from the public treasury" even without a specific statute authorizing the suit. *United States v. Wurts*, 303 U.S. 414, 415-16 (1938). The United States has broad authority to recover funds whenever its agents have wrongfully, erroneously, or illegally paid out money. *Harrod v. Glickman*, 206 F.3d 783, 790 (8th Cir. 2000); *see also United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1 (1st Cir. 2005) (recognizing Government's right to pursue recoupment of improperly paid Medicare funds through a civil action for payment by mistake or unjust enrichment); *United States v. Aging Care Home Health, Inc*., 474 F.Supp.2d. 810, 820 (W.D. La. 2007) (granting summary judgment for United States under unjust enrichment theory defendant should not have received any Medicare payments in the first place); *Visiting Nurse Ass'n v. Thompson*, 378 F.Supp.2d 75, 99 (E.D.N.Y. 2004) (granting government summary judgment in FCA/unjust enrichment case).

The obligation to refund to the Treasury money paid in error or without legal authorization will not be excused, even if the party who erroneously received it acted in "good faith" and could suffer "hardship" if required to return the funds. *Weiss v. United States*, 296 F.2d 648, 649-50 (5th Cir. 1961) (collecting cases). The government retains the right to sue for recovery of moneys paid by mistake "even if the payment resulted from the carelessness of a government official." *Mt. Vernon Coop. Bank v. Gleason*, 367 F.2d 289, 291 (1st Cir. 1966). Indeed, "where the disbursement of public funds is concerned, the government is not under the obligation of showing either that the recipient was unjustly enriched or that the balance of equities otherwise lies in its favor." *Id.* at 291. This principle has been widely recognized for more than a century. *United States v. Burchard*, 125 U.S. 176, 181 (1888) ("This is a case where the disbursing officers, supposing that a retired officer of the navy was entitled to more than it

turns out the law allowed, have overpaid him. Certainly, under such circumstances, the mistake may be corrected."); *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970) (holding, where government failed to prove defendant acted "knowingly" under FCA, "The government's alternative theory of recovery is under the common law doctrine of payment by mistake. This remedy is available to the United States and is independent of statute."); *United States v. Borin*, 209 F.2d 145, 148 (5th Cir. 1954) ("[W]e agree that payments made on invalid claims can be recaptured, and that the invalidity of the claim may be established in the action brought to recapture such payments."); *Stone v. United States*, 286 F.2d 56, 58–59 (8th Cir. 1961) ("Where monies are erroneously paid by agents of the United States, whether the error be one of fact or of law, the Government may always recover the money improperly paid.").

There is no legal requirement that the Complaint formally allege that federal common law applies in this federal case involving the federal Government and monies paid from the federal Treasury. As recognized by the Eighth Circuit, among other courts, an unjust enrichment claim is a matter of federal common law whenever the case involves, as this one does, "the determination of rights of the United States under a Nationwide program." *United States v. Applied Pharmacy Consultants, Inc.*, 182 F.3d 603, 609 (8th Cir. 1999) (affirming judgment for United States against Medicare provider who submitted inflated claims for medical devices under unjust enrichment theory); *Downey v. State Farm Fire & Cas. Co.*, 266 F.3d 675, 681-82 (7th Cir. 2001) ("when the duties or rights of the United States are at stake under a federal program, that Federal interest requires the application (and if necessary, the creation) of federal law"); *see also United States v. Indep. Sch. Dist. No. 1 of Ok-Mulgee County, Okl.*, 209 F.2d 578, 580-81 (10th Cir. 1954) (holding that federal, not state law, governs action by United States to recover erroneously paid funds, and "[w]hether . . . the asserted remedy be for money had and

received or restitution for unjust enrichment, the right to recover under controlling federal law is plain").

Defendants' brief at p. 34 incorrectly argues that the Complaint pleads an express contract claim, and that an unjust enrichment claim cannot be brought by the Government under federal common law whenever the Government is also pursuing a breach of contract claim. First, the United States' claims here are not based on a contract; rather, the Medicare and Medicaid programs are governmental benefit programs. *Rogan*, 517 F.3d at 453. Second, in the Eighth Circuit, the existence of an express contract between the parties does not bar the Government from also seeking unjust enrichment remedies. *Applied Pharmacy*, 182 F.3d at 606 (finding it would be a "gross injustice" to the United States to "apply woodenly the technical rule" that a contract claim bars an unjust enrichment claim).

Beyond these legal issues, even if the United States' claims here were based on a contract (which they are not) and were somehow inconsistent with an unjust enrichment claim, Fed. R. Civ. P. 8(d)(3) still permits a party to plead as many claims or defenses as it has, regardless of consistency.

Unlike the FCA claims, for the unjust enrichment claim, the intent of the party receiving the funds is irrelevant, and proof of fraud or wrongful conduct by the defendant is not required. *American Cleaners and Laundry Co., Inc. v. Textile Processors*, 482 F.Supp.2d 1103, 1118 (E.D. Mo. 2007) (denying a motion to dismiss because an unjust enrichment claim does not require particularized allegations of fraud); *United States v. Davis*, 666 F. Supp. 641, 644 (S.D.N.Y. 1987). Rather, to prevail under this equitable theory, the United States must show (1) that the Government had a reasonable expectation of payment, (2) the Defendants should reasonably have expected to pay, or (3) "society's reasonable expectations of person and property would be

defeated by nonpayment." *Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990); *accord United States v. Rogan*, 459 F. Supp. 2d 692, 728 (N.D. Ill. 2006). The Complaint clearly states facts from which a reasonable factfinder could conclude that the Defendants here were unjustly enriched at least by the Medicare and Medicaid programs' payments for Dr. Fonn's kickback-tainted professional services and by the amount DSM's profits resulting from the illegal scheme.

Finally, Defendants erroneously assert that the wrong parties were sued for payment by mistake and/or unjust enrichment, or that the Complaint lacks sufficient detail as to exactly who received what payments. Contrary to Defendants' argument, an unjust enrichment or payment by mistake claim can seek and recover money that was paid directly or indirectly to a defendant as long as defendants were ultimately enriched to plaintiff's detriment. *LTV Educ. Systems, Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989) (federal unjust enrichment claim enables recovery of funds from third party into whose hands the mistaken payments flowed where that party participated in and benefitted from the tainted transaction); *United States v. Mead*, 426 F.2d 118, 124-25 (9th Cir. 1970) (finding payment by mistake claim enables recovery of funds from anyone to whom mistaken payments flowed); *United States v. Honeywell Int'l*, 798 F.Supp. 12, 29 (D.D.C. 2011) (denying Rule 12 motion seeking to dismiss unjust enrichment claim seeking recovery of indirect payments). Exactly what payments flowed to which Defendants is a subject for discovery, and is not a pleading deficiency, given the flexible and remedial nature of these causes of action.

B. RESPONSES TO THE DEFENDANTS RULE 9(B) ARGUMENTS

Contrary to the arguments advanced by the Defendants in their Motion to Dismiss Pursuant to Rule 9(b) (Docket # 65), the Complaint readily satisfies the requirements of

Fed.R.Civ.P. 9(b). The Complaint more than adequately gives each Defendant notice of the "who, what, where, when and how." *United States v. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 888 (8th Cir. 2003). Rule 9(b) "was never meant to require a plaintiff to set forth every factual detail supporting its claims . . . ." *United States v. NHC Healthcare Corp.*, 115 F.Supp. 2d 1140, 1152 (W.D. Mo. 2000). Instead, the purpose of Rule 9(b)'s heightened pleading standard is 'to inhibit the filing of a complaint as a pretext for the discovery of unknown wrong, protect defendants from the harm that might come to their reputations when charged with acts of moral turpitude, and finally ensure that the allegations are particularized enough to enable defendants to prepare an adequate defense. *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 918 F.Supp. 1338, 1345 (E.D. Mo. 1996). As explained in greater detail above, the Complaint easily clears this hurdle.

Unable to mount a credible challenge to the clarity and specificity of the Complaint, Defendants' Motion to Dismiss Pursuant to Rule 9(b) sets forth a series of contrived arguments, each of which is addressed in order.

1. Allegations Regarding Spinal Manufacturers A and B

Defendants first argue on page 4 of their brief in support of their Rule 9(b) Motion that the Complaint fails to identify what remuneration was paid by spinal manufacturer "A" to the Defendants, which individual at that company participated in giving the remuneration, and the dates or times when the remuneration was paid. Defendants further argue on pages 5-7 of the brief that the Complaint fails to identify what was said or done that caused unnamed individuals at spinal manufacturer "B" to be "led to believe" that Dr. Fonn's choice of implants was related to the company's agreement to pay commissions to Ms. Seeger and DSM.

The Complaint makes clear that the remuneration at issue in Count II of the Complaint is the commissions spinal implant manufacturers A and B and other manufacturers paid to DSM while it was serving as the manufacturers' distributor for implants used by Dr. Fonn during his surgeries. (Complaint ¶¶ 87-88). Since DSM essentially had only one physician customer, Dr. Fonn, and Dr. Fonn used only one distributor, DSM, there was a tight relationship between DSM's overall commissions and the remuneration alleged in Count II. (Complaint ¶¶ 38-39). For each sale of a spinal implant device to the hospital where Dr. Fonn performed the surgeries using their implants, DSM was paid a commission by the manufacturer. (Complaint ¶¶ 33, 69). Those commissions were deposited in DSM bank accounts on dates readily available to the Defendants on DSM bank statements. These commissions were then used by Ms. Seeger to purchase various items which were given to or shared with Dr. Fonn. (Complaint ¶¶ 45, 70-71). The Complaint clearly sets forth the fact that although DSM was titled in Ms. Seeger's name alone, Dr. Fonn played a significant role in determining how DSM was operated. (Complaint ¶¶ 28, 37, 50-57). Additionally, the Complaint alleges that Dr. Fonn selected which implant to use during surgery based upon the commissions being paid to DSM by the manufacturer. (Complaint ¶¶ 50-60). With respect to spinal implant manufacturer B, the Complaint clearly alleges the dates and times of a series of communications and meetings between Defendants Fonn and Seeger and manufacturer B's executives. The Complaint describes the nature of discussions as well as the agreements that were reached. (Complaint ¶¶ 58-59).

Defendants were also specifically advised of these details during a meeting on May 12, 2014 with the Government, at which the names of spinal manufacturers A and B, along with their executives, were disclosed.

More importantly, the extraordinary level of detail Defendants demand is not required even under Rule 9(b)'s heightened pleading standard. Rule 9(b) "was never meant to require a plaintiff to set forth every factual detail supporting its claim...." *NHC Healthcare*, 115 F.Supp.2d at 1152; *Joshi*, 441 F.3d at 557 (a plaintiff is not required "to allege specific details of every alleged fraudulent claim forming the basis" of his complaint). "The sufficiency of the pleading under Rule 9(b) depends upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *O'Keefe*, 918 F.Supp. at 1345. A defendant's ability to "mount a vigorous defense" at the motion to dismiss stage is itself an indication that the pleadings are sufficiently specific. *NHC Healthcare*, 115 F.Supp.2d at 1151. To that point, and as explained above, the Defendants have crafted a lengthy, albeit ill-founded, Motion to Dismiss this case pursuant to Fed. R. Civ. P. 12(b)(6). Further, Defendants have moved to strike numerous allegations detailing the kickback scheme on the grounds that such information is immaterial. *See* Docket # 62. Defendants cannot have it both ways. The Complaint contains more than enough detail to permit these Defendants to respond to the allegations and to "mount a vigorous defense," as they have already begun to do with four separate motions. Rule 9(b) requires no more than that.

2. Allegations Regarding Remuneration from Ms. Seeger to Dr. Fonn

Defendants next contend at pages 7-13 of their Rule 9(b) brief that the Complaint fails to state with particularity the illegal remuneration passing from Ms. Seeger to Dr. Fonn. This argument is specious. Defendants acknowledge that Exhibit 1 provides "certain information" about the benefits Dr. Fonn received directly and indirectly from the kickback scheme, but they

insist that the listing of payments from the DSM accounts is not sufficient. In making this argument, Defendants simply ignore the allegations in the Complaint that together, Dr. Fonn and Ms. Seeger spent the commissions paid to DSM, (Complaint ¶ 45), and the specific allegation that the purchase price of $284,331.42 for the residence shared by Dr. Fonn and Ms. Seeger was paid directly from DSM's bank account using implant company commissions (Complaint ¶ 45).

Initially, Defendants raise some perfunctory questions as to the details of some of the items identified on Exhibit 1. Since Exhibit 1 is a compilation based upon DSM's bank records and includes among other things, dates and check numbers, it is hard to understand why Defendants are unable to discern exactly what items have been purchased, or to what use those items have been put. To the extent the Defendants require additional information about these expenditures, discovery of the bank records and invoices, not additional pleading, will solve any perceived problems.

Much of the argument that follows in Defendants' Motion does not question the amount of detail in the Complaint concerning allegations of remuneration passing from Ms. Seeger to Dr. Fonn, but rather challenges the accuracy of Exhibit 1. Defendant's Motion argues that several of the entries were for real property titled in the name of Ms. Seeger or DSM. Without conceding their accuracy, Defendant's assertions go to the substance of the allegations in the Complaint, not their adequacy under Rule 9(b). The Government need not prove its case at this point. It is only required to provide the Defendants with sufficient information to allow them to prepare a defense. *Rehab Care I*, 2013 WL 992642 at *3, ("While the Government's proof may not ultimately be sufficient to prevail, the Court concludes that the Government has stated a claim under the FCA."). The simple fact that the Defendants have been able to gather some information which they contend refutes the allegations in the Complaint is in itself proof of the

adequacy of the pleadings under Rule 9(b). *O'Keefe*, 918 F.Supp. at 1345 (To comply with Rule 9(b), allegations in a complaint must be "particularized enough to enable defendants to prepare an adequate defense.").

3. Allegations Regarding Certifications

Defendants next argue at pages 13-16 of their Rule 9(b) brief that although the Government references certifications of AKS compliance by the hospital and MWN, the complaint fails to allege that such certifications were in fact ever submitted, or at least when they were submitted. They further contend that since the Government is basing its theory of FCA liability on Defendants' AKS violations, additional detail about these certifications is essential.

The Defendants' argument ignores allegations in the Complaint. First, the Complaint alleges that Dr. Fonn personally made a number of certifications in his Medicare enrollment application, including an explicit acknowledgement by him that compliance with the Anti-Kickback Statute was a precondition of payment by Medicare (Complaint ¶¶ 16-17). Moreover, the Complaint alleges that Dr. Fonn personally submitted a number of Part B physician services claims for his examination of surgical implant patients shortly after their surgeries with DS Medical's implants. (Complaint ¶ 19). Finally, and most importantly, the Complaint alleges that both Dr. Fonn and Ms. Seeger (as well as their corporate entities) *caused* the submission of the false claims by a hospital. Defendants are well aware of the hospital where Dr. Fonn performed his surgeries, and as is evidenced by their Motion to Dismiss Pursuant to Rule 12(b)(6), are obviously aware of the certification requirements imposed on hospitals by the Medicare program. To the extent more is needed in the way of when and who filed certifications on behalf of the hospital where Dr. Fonn performed his surgeries, this evidence can be developed during discovery. As is evident from the Rule 12(b)(6) arguments the Defendants have advanced, the

allegations in the Complaint have provided them with ample information to mount a defense, which is all that is required under Rule 9(b). *O'Keefe*, 918 F.Supp. at 1345; *NHC Healthcare*, 115 F.Supp.2d at 1151.

4. Allegations Regarding Representative Examples of Actual Claims

The Defendants next contend on pages 16-18 of their Rule 9(b) brief that the Complaint fails to afford them at least some representative examples of the claims submitted pursuant to their fraudulent scheme. While acknowledging that Exhibits 2 and 3 to the Complaint provide "some information" related to Dr. Fonn's surgeries, the Defendants complain that the Exhibits fail to provide enough information. Specifically, they complain that the Exhibits do not provide dates and claims numbers, nor do the exhibits provide the full names of the patients on whose behalf the claims were filed.

When, as is the case here, a complaint alleges a systematic practice of causing the submission of false claims, an FCA complaint "must provide some representative examples of the alleged fraudulent conduct." *Joshi at* 557. The Complaint goes far beyond this minimum requirement. Exhibits 2 and 3 to the Complaint contain information about every surgery performed by Dr. Fonn involving implants acquired through DSM or other spinal implant manufacturers which resulted in allegedly kickback-tainted (and therefore false) claims being submitted to the Medicare Program. While the Exhibits appended to the publicly filed Complaint have been redacted to protect the identity and personal health information of the patients involved, the Government mailed the Defendants unredacted copies of both exhibits shortly after the Complaint was filed. If these unredacted copies were somehow lost or misplaced, the Government will resend them by mail, return receipt requested. The unredacted exhibits, however, more than satisfy any required pleading about representative examples of the false

claims at issue here, as they contain extensive information about Dr. Fonn's patients and the corresponding Medicare and Medicaid claim history. Some of this information came from Dr. Fonn, as he submitted claims to Part B of the Medicare program for his professional services.

5. Government's Pre-Filing Investigation Does Not Impose a Requirement of Greater Particularity On Its Complaint

Relying on cases from outside of the Eighth Circuit, Defendants next argue on pages 18-20 of their Rule 9(b) brief that the Government should be held to a higher standard of particularity in its Complaint due to the fact that it has had the opportunity to conduct a pre-trial investigation.

The statutory requirement that the Government conduct a pre-trial investigation in *qui tam* cases filed under the FCA[3] is related to the statutory requirement that the relator's complaint be filed under seal. 31 U.S.C. § 3730(b)(2). This requirement is intended to afford the Government an opportunity to inquire into the factual and legal basis contained in the *qui tam* complaint in order to make an informed decision whether or not to intervene in the case. *See* S. Rep. No. 345, 99th Cong., 2d Sess. (S. Rep.) at 2 (1986), *reprinted in*, 1986 Code Cong. & Admin. News 5266, 5289. It is not intended to displace the discovery that occurs in the ordinary course of civil litigation. The pre-trial investigation that is undertaken by the Government during the seal period is tantamount to the pre-filing investigation that any plaintiff's counsel is ethically obligated to undertake prior to filing a complaint. *See also* Fed. R. Civ. P. 11(b). We are unaware of any court imposing some indeterminate "higher pleading standard" upon a Complaint, as Defendants here seem to urge, simply because plaintiff's counsel ensured that the pleading met this basic obligation.

[3] *See* 31 U.S.C. § 3730(a), which requires the Attorney General to diligently investigate violations of the FCA.

Moreover, a careful reading of the three cases cited in the Defendants' brief shows that, although all three complaints were determined not to have met the requirements of Rule 9(b), the courts' decisions were not based on the fact that the plaintiff had conducted a probing pre-filing investigation, but rather on the fact that the complaints were found to contain nothing more than "conclusory statements" regarding the defendants' alleged misconduct, *Devaney v. Chester*, 813 F.2d 566, 568 (2d. Cir. 1987), or asserted "broad allegations of fraud" that lacked "sufficient detail" under Rule 9(b). *Bilard v. Rockwell Int'l Corp.,* 683 F.2d. 51, 56 (2d Cir. 1982); *United States ex rel. Monda v. Sikorsky Aircraft Corp*., 2005 WL 1925903 at 4-5 (D.Conn. Aug. 11, 2005). Unlike those cases, and as explained above, the Complaint at bar contains far more than broad or conclusory allegations of fraud.

IV. THE AVAILABILITY OF MORE DETAILED ALLEGATIONS AND EXHIBITS

The Complaint in this case is plausible and detailed and easily meets both the Rule 12 and Rule 9(b) standards. Of course, discovery will enable the parties to gather additional evidence about Defendants' intent and who received what payments. However, if the Court should find that the Complaint in any respect does not meet the requirements of either Rule, then the appropriate remedy would be to permit the Government an opportunity to amend the complaint to include even more specificity, rather than to dismiss the Complaint. 2A Moore's Federal Practice ¶ 903[5], p. 9-58; 5 Wright & Miller, Federal Practice and Procedure § 1300. This Court has broad discretion when allowing the amendment of pleadings. *City of Columbia v. Howard Co*., 707 F.2d 338, 341 (8th Cir. 1983). Failure to permit amendment of a complaint has been held to be an abuse of discretion. *Bank v. Pitt*, 928 F.2d 1108 (11th Cir. 1991). If the Court believes that more extensive pleading or exhibits are required, the Government is in a position to quickly cure any perceived oversights or omissions.

V. RELIEF REQUESTED

Wherefore, the United States respectfully requests that the Court deny Defendants' motion to dismiss pursuant to Rule 12(b) (Docket #64) and their motion to dismiss pursuant to Rule 9(b) (Docket #65) in their entirety, and grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2014, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following:

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